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IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF WISCONSIN

MARY JO LIESCH and DONALD W. LIESCH, Plaintiffs, vs. ZIMMER BIOMET, INC., f/k/a ZIMMER, INC.; ZIMMER BIOMET US, INC., f/k/a ZIMMER US, INC.; and ZIMMER BIOMET HOLDINGS, INC., f/k/a ZIMMER HOLDINGS, Defendants.	Case No. 17-cv-1036 **COMPLAINT FOR DAMAGES** (1) Negligence (2) Strict Products Liability – Design Defect (3) Strict Products Liability – Manufacturing Defect (4) Strict Products Liability – Failure to Warn (5) Negligent Misrepresentation (6) Fraudulent Misrepresentation and Concealment (7) Negligence *Per Se* (8) Punitive Damages (9) Loss of Consortium **DEMAND FOR JURY TRIAL**

Plaintiffs MARY JO LIESCH and DONALD W. LIESCH ("Plaintiffs"), by their undersigned attorneys, bring this Civil Action Complaint against Defendants ZIMMER

BIOMET, INC. f/k/a Zimmer, Inc., ZIMMER BIOMET US, INC. f/k/a Zimmer US, Inc., and ZIMMER BIOMET HOLDINGS, INC. f/k/a Zimmer Holdings, Inc. (collectively, the "Zimmer Defendants" or "Zimmer" or "Defendants") upon information and belief, investigation and personal knowledge, and at all times hereinafter mentioned, allege as follows:

INTRODUCTION

1. This products liability action relates to the design, development, manufacture, testing, marketing, promotion, distribution, and sale of Zimmer's defective hip implant components known as the Zimmer VerSys Hip System Femoral Head 12/14 Taper ("Zimmer VerSys femoral head") and the Zimmer M/L Taper Prosthesis with Kinectiv Technology Modular Neck ("Zimmer M/L Taper") (collectively, the "Defective Devices" or "the Products" or "Zimmer hip joint implant products").

2. The Products were surgically implanted in Plaintiff Mary Jo Liesch's right hip on May 19, 2010, and in her left hip on September 11, 2013.

3. On November 12, 2015, Mrs. Liesch required revision surgery of her left hip because the Products were causing metal debris to be released into her hip causing adverse local tissue reaction and elevated metal ions in her blood (a condition known as metallosis) and therefore, were defective. This surgery caused Plaintiff to suffer significant injuries, including great pain and agony that restricted her ability to engage in activities of daily living as well as the physical activities that she enjoys.

4. Plaintiff underwent revision surgery of her right hip on April 24, 2017, due to metallosis and adverse local tissue reaction caused by the defective devices implanted in her right hip. Plaintiff suffered further pain, suffering, emotional distress and economic losses. Both Plaintiffs Mr. and Mrs. Liesch suffered loss of consortium and were forced to expend money and resources unnecessarily.

PARTIES

5. Plaintiffs Mary Jo Liesch and Donald W. Liesch are citizens and residents of Abrams, Oconto County, Wisconsin. They are married to one another and were married at all times relevant to this action.

6. Defendant Zimmer Biomet Holdings, Inc. formerly known as Zimmer Holdings, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana, 46580-2746. At all relevant times, Zimmer Biomet Holdings, Inc. was the publicly traded holding company with wholly owned subsidiaries, that it controlled, which designed, manufactured, marketed, supplied and sold to distributors, physicians, hospitals, patients and medical practitioners the Products to be surgically implanted in patients throughout the United States, including in the State of Wisconsin.

7. On April 24, 2014, Zimmer Holdings, Inc. entered into an agreement to merge with LVB Acquisition, Inc., the parent company of Biomet, Inc. After the merger, Zimmer Holdings, Inc. was renamed Zimmer Biomet Holdings, Inc. and Zimmer, Inc. was renamed Zimmer Biomet, Inc.

8. Defendant Zimmer Biomet, Inc., formerly known as Zimmer, Inc., is a Delaware corporation with its principal place of business at 1800 West Center Street, Warsaw, Indiana, 46581-0708.

9. Zimmer Biomet, Inc. is a wholly owned subsidiary of Defendant Zimmer Biomet Holdings, Inc.

10. Defendant Zimmer Biomet, Inc. solicits business within the State of Wisconsin and derives substantial revenue from goods used and sold in the State of Wisconsin.

11. At all times mentioned in this Complaint, Defendant Zimmer Biomet, Inc. was engaged in the business of manufacturing, compounding, assembling, inspecting, packaging,

designing, testing, analyzing, recommending, merchandising, advertising, promoting, supplying and/or selling to wholesalers, jobbers, distributors and/or retailers for sale to physicians, hospitals, medical practitioners and the general public, the Products for use in hip replacement surgery, including the Products at issue in this lawsuit.

12. Defendant Zimmer Biomet US, Inc. is a duly organized foreign corporation doing business at the premises known as 345 East Main Street, Warsaw, State of Indiana.

13. Defendant Zimmer Biomet US, Inc. is a wholly-owned subsidiary of Zimmer Biomet, Inc.

14. At all times mentioned in this Complaint, Defendant Zimmer Biomet US, Inc. was engaged in the businesses of manufacturing, compounding, assembling, inspecting, packaging, designing, testing, analyzing, recommending, merchandising, advertising, promoting, supplying and/or selling to wholesalers, jobbers, distributors and/or retailers for resale to physicians, hospitals, medical practitioners and the general public, the Products for use in hip replacement surgery.

15. At all relevant times, each and all of the aforementioned Defendant Zimmer entities were engaged in the design, development, manufacture, distribution, fabrication, wholesale, retail, supply, marketing and/or service of the Products.

16. At all relevant times, each and all of the Defendant Zimmer entities regularly sold and shipped the Products into the State of Wisconsin, and in particular, provided the Products to St. Mary's Hospital in Green Bay, Wisconsin, and to Plaintiff's implanting surgeon, Dr. Michael O'Reilly, in Green Bay, Wisconsin, for implantation into human patients, including Plaintiff Mary Jo Liesch.

17. At all relevant times, Zimmer Defendants represented that the subject orthopedic prosthetic hip components, and specifically the products at issue in this lawsuit, were safe, fit for use, free from defects and suitable for implantation into human patients, including Plaintiff Mary Jo Liesch.

18. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority. At all relevant times each Defendant was responsible for each other's actions and inactions; and, each Defendant acted on behalf of each other Defendant.

19. At all relevant times, Defendants possessed a unity of interest between themselves and Zimmer, and Zimmer exercised control over its subsidiaries and affiliates. As such, each Defendant is responsible individually, as well as jointly and severally, and therefore each is liable to Plaintiffs for Plaintiffs' injuries, losses and damages.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants, and because Plaintiffs allege an amount in controversy in excess of $75,000, exclusive of interest and costs.

21. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in the State of Wisconsin. At all relevant times, Zimmer Defendants transacted, solicited, and conducted business in Wisconsin through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Wisconsin.

22. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(c) because Defendants are all corporations

that have substantial, systematic, and continuous contacts in the Eastern District of Wisconsin and are all subject to personal jurisdiction in this District.

FACTUAL ALLEGATIONS

I. MARY JO LIESCH and DONALD W. LIESCH

23. On or about May 19, 2010, Plaintiff Mary Jo Liesch underwent a total hip arthroplasty of her right hip with insertion of the Products. The surgical procedure was performed by Michael O'Reilly, M.D., at St. Mary's Hospital in Green Bay, Wisconsin.

24. On or about September 11, 2013, Plaintiff Mary Jo Liesch underwent a total hip arthroplasty of her left hip with insertion of the Products performed by Michael O'Reilly, M.D. at St. Mary's Hospital in Green Bay, Wisconsin.

25. At the time that Plaintiff underwent her total right and left hip arthroplasties, she received defective, dangerous, hazardous and unsafe products designed, manufactured, developed, tested, promoted, distributed and sold by the Zimmer Defendants.

26. After the implantation of the Products, Plaintiff Mary Jo Liesch began experiencing significant pain and discomfort in her left hip, groin, and gluteal region with increasing weakness of her quadriceps.

27. Diagnostic workup revealed the absence of device loosening, infection, malposition, or any other explanation for Plaintiff's symptoms.

28. Further diagnostic workup revealed blood test results indicating the presence of heavy metal ion contamination of her blood and MRI results revealed adverse local tissue reaction around the prosthesis and large pseudotumors in her left hip abductors and left iliopsoas muscles. Plaintiff Mary Jo Liesch was suffering from destruction of muscle and developed significant dysfunction of her femoral nerve caused by the large pseudotumors.

29. Based upon these findings and in light of worsening symptoms, Plaintiff underwent a complex revision surgery of her left prosthesis on November 12, 2015, performed by Donald Hackbarth, M.D. and Peter Rossi, M.D. at Froedtert Health Center for Advanced Care ("Froedtert Health") in Milwaukee, Wisconsin.

30. On November 12, 2015, Plaintiff Mary Jo Liesch underwent two operations. The first operation was the revision of the left hip arthroplasty revising the femoral stem and the acetabular liner; resection of large pseudotumor formation involving the quadriceps musculature and abductor musculature, including the gluteus medius, minimus, and maximus muscles; and repair of the abductor tendon mechanism. The second operation was to excise the pseudotumor from her left hemipelvis that was causing femoral nerve compression.

31. During the first operation on November 12, 2015, it was discovered that, in fact, there was significant corrosion of the Zimmer modular neck component.

32. Eighteen days after her complex revision surgery, on November 30, 2015, Plaintiff Mary Jo Liesch began experiencing extensive drainage from her incision. She presented at Froedtert Health and underwent an incision, drainage and debridement of the left hip incision and exchange of the polyethylene liner, trunnion, and femoral head prosthetic components. Following the surgery, Mrs. Liesch had a wound VAC placed and began antibiotics. Cultures taken from the surgery grew no bacteria and she was discharged on December 3, 2015, and required to wear an abductor orthosis brace. On December 13, 2015, Dr. Hackbarth removed the wound VAC.

33. Due to the large pseudotumor, Mrs. Liesch experienced dense femoral nerve palsy after the revision surgery and was still experiencing weakness in her quadriceps three months after surgery despite diligent physical therapy.

34. The large pseudotumor additionally caused significant abductor dysfunction. Due to the abductor dysfunction, as well as the femoral nerve palsy, in early March 2016, Mrs. Liesch's left hip spontaneously dislocated while she attempted to scoot herself back on a bench. A hip dislocation is extremely painful. Mrs. Liesch had a closed reduction at a local emergency room and was placed back into the abductor orthosis brace, which was not to be removed but for bathing.

35. Again, in April 2016, Mrs. Liesch experienced another dislocation of her left hip when she was arising from her recliner. She presented at the local emergency room for a closed reduction and remained in her abductor orthosis brace.

36. Due to the recurrent dislocations, Mrs. Liesch underwent a second revision of her acetabular component to a locked acetabulum on April 28, 2016, performed by Dr. Hackbarth at Froedtert Health Center.

37. Following her discharge on April 30, 2016, Mrs. Liesch continued to wear the abductor orthosis brace for a week and a half and remained partial weight bearing with a walker through June 2016.

38. In September 2016, Mrs. Liesch was still using a cane for mobility. She experienced significant weakness in her abductors on the left and nearly absent function of the femoral nerve with very weak quadriceps on the left. She also began experiencing a significant clicking and snapping from the front-side aspect of her left hip, likely caused by a prominent left greater trochanter.

39. Mrs. Liesch was discharged from formal physical therapy on November 30, 2016. Her physical therapist, Diane Wauters, opined that she may not see any further motor return and may require a cane indefinitely.

40. Mrs. Liesch began experiencing pain in her right hip in the winter of 2016. Blood work revealed elevated metal ions. MRI results demonstrated adverse local tissue reaction around the prosthesis and pseudotumors around the right hip. As a result, Mrs. Liesch underwent a revision of her right hip prosthesis on April 24, 2017.

41. As a result of the defective hip implants, Plaintiffs' well-being has suffered, and will continue to suffer. Mrs. Liesch and her husband, Donald W. Liesch have expended and will continue to expend money for her care, and expect to continue to suffer these losses and damages due to her ongoing pain, debilitation, and significant emotional distress.

42. Spouse Plaintiff Donald W. Liesch has lost the society and love and affection of his beloved spouse.

II. BACKGROUND ON ARTIFICIAL HIPS AND HIP REPLACEMENT DEVICES

43. The human hip joint consists of two parts: a ball and a socket. A portion of the pelvic bone forms a cup-shaped socket; the ball at the top of the thigh bone fits into it. The ball is surrounded with cartilage which, in a healthy hip joint, allows the ball to move smoothly within the socket. Conditions such as osteoarthritis and avascular necrosis can cause degeneration of the hip joint such that hip replacement is required. A hip implant is designed to replicate the human anatomy—that is, the relatively simple ball and socket structure of the human hip joint. Total hip replacement surgery involves implanting an artificial ball and socket into the patient.

44. The artificial hip implantation process requires a surgeon to insert a metal cup with a smooth lining into the patient's diseased pelvic socket. The lining serves the same purpose as natural cartilage: allowing for smooth movement of the ball portion of the thigh bone. The diseased or degenerated ball part of the thigh bone is then removed and replaced by a metal or sometimes ceramic ball mounted onto a thin metal stem. The metal stem is then fit into the

thigh bone. Finally, the ball is placed securely into the pelvic socket that has been fitted with the artificial metal cup, where it should move easily, without friction or pain to the patient.

45. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications include rheumatoid arthritis, avascular necrosis, traumatic arthritis, protrusion acetabuli, certain hip fractures, benign and malignant bone tumors, arthritis associated with Paget's disease of the bone, ankylosing spondylitis and juvenile rheumatoid arthritis. The aims of the procedure are pain relief and improvement in hip function. Hip replacement is usually considered only once other therapies, such as pain medications, have failed.

46. Total hip arthroplasty ("THA"), or total hip replacement, is a common medical procedure performed on more than 420,000 patients in the U.S. each year. It is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma. Traditional devices to replace degenerative hips utilize implantable metal or ceramic heads fitting into a modular metal-backed polyethylene bearing. One concern that historically plagues successful THAs is the wear of the bearing. As the THA becomes more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear.

III. ZIMMER M/L TAPER WITH KINECTIV TECHNOLOGY and the VERSYS 12/14 FEMORAL HEAD

47. The Zimmer M/L Taper with Kinectiv Technology stem and neck are Titanium® alloy implants used for hip replacements that allow the surgeon to fit the implant specifically to the patient. During hip replacement surgery, the damaged portions of the hip joint are removed and replaced with an integrated system of products, which includes the femoral stem and neck.

48. The Zimmer VerSys femoral head is used in connection with the M/L Taper with Kinectiv Technology.

49. The Zimmer M/L Taper with Kinectiv Technology is used with a spray coating called a "Circumferential Plasma Spray" intended to facilitate surgical placement. The device components, together with the acetabular cup are intended to be used in small women and patients with adequate bone stock, like Mary Jo Liesch.

50. The Zimmer M/L Taper with Kinectiv Technology was approved pursuant to a 510(k) on or about July 30, 2007, and Zimmer proceeded to sell the components to be used together with the Zimmer VerSys femoral head.

51. Zimmer introduced the M/L Taper with Kinectiv Technology as part of a modular system that had a modular stem and neck components that were intended to offer the orthopedic surgeon more options in the operating room. The three failure modes were considered when developing and manufacturing this modular neck and stem system:

a. Proximal implant strength;

b. Fretting and corrosion; and,

c. Junction stability.

52. The Zimmer VerSys femoral heads were manufactured with Zimaloy® Cobalt and Chromium.

53. The Zimmer VerSys femoral heads were first tested in 1996 by Zimmer to be used with cobalt chromium tapers and with titanium alloy tapers. According to Zimmer, there was not significant fretting or corrosion using either form of taper.

54. The Zimmer M/L Taper with Kinectiv Technology device paired with a VerSys femoral head device were bench tested and the test results were represented to be adequate and

that this combination of modular components performed satisfactorily. However, the test results show a different picture and demonstrate increased fretting and corrosion and fatigue when these parts were combined.

55. The M/L Taper with Kinectiv Technology was first launched in Australia in 2008.

56. In 2008, when Zimmer first introduced the M/L Taper with Kinectiv Technology, it represented that after five years of testing, that this modular neck implant design "demonstrates less fretting/corrosion wear debris than a clinically successful standard 12/14 neck taper with long offset femoral head." Hertzler, Justin S., et al " Performance Evaluation of Kinectiv Technology", 2008, p.2.[1] This was written after fifty (50) components had been bench tested by Zimmer employees, Justin Hertzer, Steven Meulink and Todd Johnson, Ph.D., to examine for fatigue, fretting/corrosion and strength.

57. Through 2014, 2,843 of these devices were implanted in Australia. The Zimmer M/L Taper with Kinectiv Technology was specifically identified in the Australian national registry of devices as early as the 2013 annual report as having revision rates significantly higher than other total hip replacement prosthetics, with revision rates greater than two (2) times that of other conventional hip implants. The most prominent cause of these unusually high revision rates was "metal-related pathology," which was more than twelve (12) times more likely to be the reason for a revision surgery with the M/L Taper with Kinectiv Technology was used with the VerSys ball, as compared to other total hip revision systems.

58. Plaintiff Mary Jo Liesch's cause for revision was metal-related pathology.

59. Defendant Zimmer failed to disclose the greater risk of wear, metal debris and corrosion associated with these devices.

[1] *Available at* http://prod-www.web.zimmer.com/content/pdf/en-GB/ML_Taper_with_Kinectiv_White_Paper_(97-7713-010-00)_(2010).pdf.

60. Defendant Zimmer used its distributors and its sales representatives to communicate with the doctors, such as Dr. O'Reilly and the doctors at St. Mary's Hospital.

61. Defendant Zimmer and its sales representatives intentionally or negligently failed to accurately describe the risks of fretting and corrosion, release of metal debris and metal ions into the surrounding tissue and the blood associated with the use of the M/L Taper with Kinectiv Technology and the VerSys femoral head.

62. Had Zimmer disclosed the accurate information about this particularly dangerous failure mode, i.e., fretting and corrosion, Plaintiff and her surgeon may never have used these components.

63. Had Zimmer published the results of the studies and information made available based on the Australian implants, accurate information would have been made available to Plaintiff's surgeon and other implanting physicians who used Zimmer components in hip implant surgeries.

64. Despite their knowledge of the serious injuries associated with use of these Products, the Zimmer Defendants engaged in a marketing and advertising program which, as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the these Products were safe.

65. At all relevant times, Zimmer knew or should have known that the M/L Taper with Kinectiv Technology and the VerSys femoral head were not safe for the patients in whom it was implanted, including Plaintiff, because of the unacceptable failure rate.

66. Notwithstanding the knowledge of predicted failures with the defective devices, Zimmer continues to sell these devices for implantation in patients.

67. Plaintiff Mary Jo Liesch has not only suffered physical injuries, she has endured and continues to endure an unacceptable increase in the risk of severe pain and disability, with or without a costly and painful additional revision surgery. The revision surgeries were invasive and painful and were necessitated by these defective devices. It is unknown what were the long term effects of the increased metal ion levels in her blood and tissue. However, Mrs. Liesch lost a good bit of muscle tissue in and around her pelvis and abductors.

68. Mr. and Mrs. Liesch have had to expend large sums of money to care for Mrs. Liesch. Plaintiffs have and will in the future have expenses and loss of income as a result of the injuries and damages they suffered as a result of Zimmer's omission and misconduct.

IV. VIOLATIONS OF FEDERAL REGULATIONS

69. The Medical Device Amendments of 1976 ("MDA") to the Food Device Cosmetic Act ("FDCA") established the current regulatory framework for medical device approval.

70. The MDA contains a three-class classification system for medical devices. Class I devices pose the lowest risk to consumers' health, do not require FDA approval for marketing, and include devices such as tongue depressors. Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents. Finally, Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery.

71. On or about July 30, 2007, the FDA cleared the Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology System. Based on Zimmer's submission, the FDA found that the devices were substantially similar to a legally marketed predicate device, and allowed Zimmer to market this hip component.

72. According to the U.S. Supreme Court in *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 346 (2001), the Supreme Court explained that demonstrating that a device qualifies for this, known as the "§ 510(k) process," means that: "[s]ection 510(k) submissions must include the following: 'Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use,' 21 CFR § 807.87(e) (2000); and must include "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," § 807.87(f); "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," § 807.87(k); and "any additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," § 807.87(l). Here, the M/L Taper with Kinectiv Technology and the VerSys femoral head were cleared pursuant to this 510(k) process.

73. The FDCA requires cleared medical devices to be demonstrated to be safe and effective for each intended use.[2] Not only is the medical device itself part of the 510(k) process, but so is the labeling and packaging that comes with it.

74. A manufacturer is required to give adequate directions for the use of a medical device such that a "layman can use a device safely and for the purposes for which it is intended"[3], and conform to section 801.15 requirements governing the appearance of the label.

[2] 21 U.S.C. § 360e(c)(2)(A)(iv) (2012).
[3] 21 C.F.R. § 810.5 (2012).

75. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling.[4] False and misleading labeling is considered misbranding,[5] which is prohibited.[6]

76. The distribution of a "misbranded" medical device is prohibited pursuant to 21 U.S.C. §§ 331(a), (k) (2012) and 21 U.S.C. § 352(f) (2012).

77. The FDCA provides that a medical device is misbranded if, among other things, the labeling did not contain adequate directions for use, which includes critical information about adverse events. Adequate directions for use cannot be written including adverse events when the manufacturer has failed to disclose those adverse events to the FDA. Therefore, the labeling becomes inadequate and the product is misbranded.

78. Federal law requires a manufacturer to ensure that any warranty statements it voluntary makes are truthful, accurate, not misleading, and consistent with applicable federal and state law.[7]

79. Under the FDCA, medical device manufacturers are prohibited from introducing the adulteration or misbranding of any medical device into interstate commerce.[8]

A. The FDA, By Its Regulations and 510(k) Process Prohibits Misleading or False Promotion and Marketing Activities

80. Under the FDCA and FDA's implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed misleading if they omit or ignore certain information about the product's risks.

[4] 21 U.S.C.§ 321 (n)(2012).
[5] 21 U.S.C.§ 352 (a), q(1) (2012).
[6] 21 U.S.C.§ 331(b).
[7] 21 U.S.C. § 331(b) (effective 2013).
[8] *Id.*

81. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices.[9]

82. A medical device shall be deemed to be misbranded if its labeling is false or misleading in any particular. Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in a promotional piece.[10]

B. After a Medical Device Is Cleared, The Manufacturer Still Has Requirements, Including General reporting Requirements to the FDA Mandated by Federal Regulations.

83. A medical device manufacturer's obligations do not end with the 510(k) clearance by the FDA.

84. Even after clearance, manufacturers are required to report to the FDA "no later than 30 calendar days after the day: the manufacturer receive[s] or otherwise become[s] aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer:

a. May have caused or contributed to death or serious injury; or

b. Has malfunctioned and this device or a similar device [likewise marketed by the manufacturer] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.[11]

85. These reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession.

[9] *See* 21 U.S.C. § 352(a), (n), (q), &(4) (2012).
[10] 21 U.S.C.§ 321(n)(2012); 21 C.F.R. §§ 1.21, 202.1(e)(5)(iii) (2012).
[11] 21 C.F.R. § 803.50(a) (2012); 21 U.S.C. § 360i(a) (2012).

86. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event.[12]

87. Manufacturers are required to make periodic reports to the FDA regarding cleared devices, such reports to include summaries of:

a. Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant; and,

b. Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.[13]

88. The medical device manufacturer has a continuing duty to monitor the product after FDA clearance and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.

89. The manufacturer is obligated to inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer knows or reasonably should know.[14]

90. The FDA can revoke its clearance based on these post-approval reports.[15]

91. The manufacturer must establish internal procedures for reviewing complaints and event reports.[16] Medical device manufacturers are required by federal regulation to "establish and maintain" an adverse event database.[17] Pursuant to federal regulations,

[12] 21 C.F.R. § 803.50(b)(3).
[13] 21 C.F.R. § 814.84 (b)(2) (2012).
[14] *Id.*
[15] 21 U.S.C. §§ 360(e)(1), 360(h)(e) (2012).
[16] 21 C.F.R. § 820.198(a) (2012).
[17] 21 C.F.R. § 803.1(a) (2012).

manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device.[18]

92. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health.[19]

93. Manufacturers must disclose any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events.[20]

94. Device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals.

95. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices

[18] 21 C.F.R. § 803.52 (2012).
[19] 21 U.S.C. § 360 (i).
[20] *See* 21 C.F.R. § 806 (2012)

manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal.[21]

96. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses.

97. Manufacturers must also meet quality standards in manufacture and production of the devices.

98. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions; investigate the cause of nonconforming products; and, take corrective action to prevent recurrence.

99. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary.

100. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance.

101. Zimmer failed to comply with several of these requirements which led to the devices being on the market for use by Plaintiff's doctor.

102. Zimmer failed to comply with many of these above mentioned FDA regulations and requirements.

103. Zimmer failed to report adverse events timely to the FDA.

104. Zimmer failed to investigate and correct problems with the product.

[21] *See* 21 C.F.R. § 806 (2012)

C. Post Clearance of the Product, The FDA, By Its Regulations And PMA Process, Requires A Manufacturer To Follow Good Manufacturing Practices.

105. Under 21 C.F.R. § 820.1(a) (2012) of the Quality System (QS) Regulation for Medical Devices, current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FDCA). This part establishes basic requirements applicable to manufacturers of finished medical devices.

106. 21 C.F.R. § 820.5 (2012) "Quality Systems," the FDA regulations state, "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

107. 21 C.F.R. § 820.3(z)(2) (2012) "Design validation," means the manufacturer must establish objective evidence that device specifications conform with user needs and intended use(s)."

108. 21 C.F.R. § 820.22 (2012): "Quality Audit" states: "Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system."

109. 21 C.F.R. § 820.160(a) (2012): "Distribution" states: "Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution."

110. 21 C.F.R. § 820.170(a) (2012): "Installation" states: "Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device."

111. 21 C.F.R. § 803 (2012), states: "Manufacturers must include information that is reasonably known to the manufacturer, timely make Medical Device Reporting ("MDR") submissions, define the procedures for implementing corrective and preventative actions, and review sampling methods for adequacy of their intended use."

112. 21 C.F.R. § 820.100 (2012) "Corrective and Preventive Action" states: (a) [e]ach manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; and

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

D. Zimmer's Conduct in Violation of the FDCA

113. Zimmer violated these FDCA statutes and accompanying regulations by:

a. falsely and misleadingly promoting M/L Taper with Kinectiv Technology and the VerSys Femoral Head;

b. failing to report to the FDA adverse events;

c. failing to timely conduct failure investigations and analysis;

d. failing to timely report any and all information concerning product failures and corrections;

e. failing to timely and fully inform FDA of unanticipated adverse effects, including device corrosion, increases in the incidence of adverse effects, and device failures necessitating a labeling, manufacturing or device modification;

f. failing to conduct necessary design validation;

g. selling and distributing a misbranded and adulterated product through interstate commerce; and,

h. failing to immediately disclose the metallosis risk from the fretting and corroding failure of these Products after implantation in patients.

114. Zimmer's violation of these FDCA statutes and accompany regulations, as discussed above, constitutes violation of the state law tort causes of action alleged in this Complaint, as set forth herein.

115. Zimmer's violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the use of the M/L Taper with Kinectiv Technology and the VerSys Femoral Head; and, generally, and directly caused or significantly contributed to the use of these Defective Devices in Plaintiff and Zimmer's misconduct in this regard thus directly caused or contributed to Plaintiff's injuries and damages.

CLAIMS FOR RELIEF

CLAIM ONE

NEGLIGENCE

116. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

117. At all times mentioned in this complaint, Zimmer had a duty to properly manufacture, compound, test, inspect, package, distribute, market, examine, maintain, and prepare for use and sell its above-mentioned hip joint implant products.

118. In placing the Products onto the market, Zimmer was careless, reckless and negligent by virtue of the following acts or omissions, which are listed herein as illustrative and not exhaustive:

a. Failure to adequately and properly design and manufacture the aforesaid products; there were alternative safer designs of the hip prosthetic components that had a much lower incidence of fretting, corrosion, release of metal ions, metallosis, and adverse tissue reactions;

b. Distributing the products when Zimmer knew, or in the exercise of reasonable care should have known, that its hip joint implant products were of such a nature that if such products were not properly manufactured, compounded, tested, inspected, packaged, distributed, marketed, examined, and/or sold, such products were likely to cause serious injury in patients;

c. Negligently and carelessly manufacturing, packaging, distributing, recommending, displaying, selling, examining and failing to examine its above-mentioned hip joint implant products that such were dangerous and unsafe for the user and for the purpose for which the products were intended;

d. Failing to adequately and properly test and inspect the products before placing them on the market;

e. Failing to have adequate or appropriate quality controls over the design and/or manufacturing process;

f. Failing to warn the public in general, Dr. Michael O'Reilly, and the medical community and the patients, such as Mary Jo Liesch in particular, of the risks and dangers associated with the use of its products;

g. Failing to take reasonably prompt steps to withdraw the products, notify learned intermediaries such as physicians, or otherwise remove the products from the stream of commerce as soon as the defects therein were discovered; and

h. Zimmer failed to adequately disclose the fretting and corrosion caused by these devices to the medical community, to the medical journals and to the medical community at large who depended on Zimmer for accurate and truthful information about its products so that the physicians could make appropriate judgments and choices of products for their patients;

i. And, as the information increased that there was an increasing risk of failure, Zimmer failed to disclose it to the medical community and the patients who had been implanted with these devices that there was a previously undisclosed increased rate of corrosion, fretting and the release of metal debris and metal ions.

119. The Zimmer Defendants were negligent in carrying out the manufacturing, retailing, design, wholesaling, testing, advertising, promotion, marketing, sales and/or distribution of the Products.

120. The personal injuries sustained by Mary Jo Liesch were caused by the latent effects of her exposure to and implantation with the defective, dangerous, hazardous and unsafe products designed, manufactured, distributed and supplied by Zimmer, which defects were not discovered by the Plaintiff and could not have been discovered through the exercise of reasonable diligence by Plaintiff until, at the earliest, in or about November 2015, when she received imaging results, blood and other test results evidencing adverse local tissue reaction surrounding her hip implant and metallosis.

121. As a proximate result of the above-mentioned carelessness and negligence of Zimmer, Zimmer's Products caused severe and permanent injuries to Plaintiff's body and thereby proximately caused Plaintiffs to sustain the injuries and damages as alleged in this Complaint.

122. As a further proximate cause of Zimmer's negligence, Plaintiffs were required to and did employ physicians and surgeons to examine, treat, and care for Mrs. Liesch, and did incur medical, hospital, pharmaceutical, and incidental expenses, and will continue to incur such medical, hospital, pharmaceutical and incidental expenses in the future. In addition, Zimmer's conduct proximately caused Mary Jo Liesch to live under a continued likelihood of increased

risk of developing medical problems associated with the presence of metal ions in her body, and attendant emotional stress that constantly is present.

123. By reason of the foregoing, Plaintiff Mary Jo Liesch has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for herself as a result of the injury and damages she has suffered; and Plaintiff Donald W. Liesch has lost the society, comfort and consortium of his beloved wife.

124. The foregoing was caused without any negligence on the part of Plaintiffs contributing to these injuries and damages.

125. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest and costs.

126. Defendants' conduct as alleged above was malicious, intentional and outrageous willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM TWO

STRICT LIABILITY: DEFECTIVE DESIGN

127. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

128. Prior to Mrs. Leisch's total hip arthroplasty, Zimmer, as the designer, manufacturer, retailer, wholesaler, fabricator, supplier, and/or distributor of the Products were under a strict duty not to design, manufacture, distribute, market or otherwise place into the stream of commerce a product that was defective, dangerous, hazardous or otherwise unsafe to human health.

129. As a direct and proximate result of Zimmer's placing the defective hip implant products onto the market, Plaintiff was implanted with these defective products.

130. Zimmer is strictly liable to Plaintiffs for manufacturing, designing, retailing, distributing, wholesaling, modifying, fabricating, supplying and/or placing on the market and in the flow of commerce, defective products knowing that the Products would be used by the public and particularly by the recipients without inspection. The Products were not fit for their intended purpose; the risks inherent in the design of the Products outweighed the benefits; and the Products were more dangerous than Plaintiff or her doctor anticipated. All of these defects proximately caused the injuries and damages to Plaintiff as alleged.

131. Zimmer's Products were defective, unsafe and unreasonably dangerous for use in hip arthroplasty surgery and caused and will continue to cause grievous and debilitating bodily injury when used for such purposes.

132. The defective condition of Zimmer's above-mentioned hip joint implant products existed when the product left the manufacturer's control.

133. Zimmer's above-mentioned hip joint implant products reached Plaintiff and her surgeons without substantial change.

134. Zimmer knew that its hip joint implant products were to be used by the user without inspection or testing for defects in the product.

135. Plaintiff was injured by the defect in the product. The product as composed caused fretting and corrosion at the juncture where the Taper met the femoral head. That resulted in the release of metal ions and debris into the surrounding tissue causing Plaintiff to suffer an adverse tissue reaction, due to the death of the tissue from the metal ions. Had Zimmer

sold Plaintiff's surgeon a safer, alternative design existed, then Plaintiff would never have been injured by this dangerous and defective set of products, designed and sold to be used together.

136. Zimmer knew and had reason to know that there were safer alternative products available on the market at the time the defective products were sold in this case. In fact, Zimmer manufactured and sold Zimmer hip prosthetic devices that were ceramic and /or were the same metals to avoid any problem consistent with metallosis due to the implant failure.

137. Plaintiff neither knew, nor had reason to know, at the time of the use of Zimmer's products, or at any time prior to such use, of the existence of the above-described defect or that there were other, safer hip implants available on the market at the time of her total hip arthroplasty.

138. As a direct and proximate result of being implanted with Zimmer's defective, dangerous, hazardous and unsafe hip implant products, Plaintiff Mary Jo Liesch has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for herself as a result of the injury and damages she has suffered; and Plaintiff Donald W. Liesch has lost the society, comfort and consortium of his beloved wife. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

139. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM THREE

STRICT LIABILITY: MANUFACTURING DEFECT

140. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

141. Prior to Plaintiff's total hip arthroplasty, Zimmer, as the designers, manufacturers, retailers, wholesalers, fabricators, suppliers, and/or distributors of the hip joint implant products were under a strict duty not to design, manufacture, distribute, market or otherwise place into the stream of commerce a product that was defective, dangerous, hazardous or otherwise unsafe to human health.

142. As a direct and proximate result of Zimmer's placing the said defective hip implant products into the market, Plaintiff was implanted with same.

143. The hip joint implant products implanted into Plaintiff, as manufactured, deviated from Zimmer's design and/or internal quality standards.

144. Zimmer is strictly liable to Plaintiffs for manufacturing, designing, retailing, distributing, wholesaling, modifying, fabricating, supplying and/or placing on the market and in the flow of commerce, defective products knowing that the products would be used by the public and particularly by the recipients without inspection. The hip joint implant products were not fit for their intended purpose and/or the risks inherent in the design of the hip joint implant products outweighed the benefits and/or the hip joint implant products were more dangerous than Plaintiff anticipated. All of these defects proximately caused the injuries and damages to Plaintiff as alleged herein.

145. Zimmer's above-mentioned hip joint implant products were defective, unsafe and unreasonably dangerous for use in hip arthroplasty surgery and caused and will continue to cause grievous and debilitating bodily injury when used for such purposes.

146. The defective condition of Zimmer's above-mentioned hip joint implant products existed when the product left the manufacturer's control.

147. Zimmer's above-mentioned hip joint implant products reached Plaintiff and her surgeons without substantial change.

148. Zimmer knew that its hip joint implant products were to be used by the user without inspection for defects in the product.

149. Plaintiff was injured by the manufacturing defect in the product. The product as manufactured caused fretting and corrosion at the juncture where the taper met the femoral head. That resulted in the release of metal ions and debris into the surrounding tissue causing Plaintiff to suffer an adverse tissue reaction, due to the death of the tissue from the metal ions. Had Zimmer sold Plaintiff's surgeon a safer, alternative design, then Plaintiff would never have been injured by this dangerous and defective set of products, designed, manufactured, and sold to be used together.

150. Zimmer knew and had reason to know that there the hip joint implant products were defectively manufactured at the time it sold and distributed the products.

151. Plaintiff neither knew, nor had reason to know, at the time of the use of Zimmer's products, or at any time prior to such use, of the existence of the above-described manufacturing defect or that there were other, safer hip implants available on the market at the time of her total hip arthroplasty.

152. As a direct and proximate result of being implanted with Zimmer's defective, dangerous, hazardous and unsafe hip implant products, Plaintiff Mary Jo Liesch has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for herself as a result of the injury and damages she has suffered; and Plaintiff Donald W. Liesch has lost the society, comfort and consortium of

his beloved wife. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

153. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM FOUR

STRICT LIABILITY: FAILURE TO WARN

154. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

155. At the time the hip joint implant products were supplied to Plaintiff, the products were defective as a result of Zimmer's failure to adequately test for safety, and to give adequate warnings, labeling, or instructions regarding the development of medical problems associated with the presence of metal ions in Plaintiff's body and/or intended users as described herein and other dangers which might be associated with the use of the hip joint implant.

156. Zimmer's above-mentioned hip joint implant products were defective, unsafe and unreasonably dangerous for use in hip arthroplasty surgery and caused and will continue to cause grievous and debilitating bodily injury when used for such purposes.

157. The defective condition of Zimmer's above-mentioned hip joint implant products existed when the product left the manufacturer's control.

158. Zimmer's above-mentioned hip joint implant products reached Plaintiff and her surgeons without substantial change.

159. Zimmer failed to adequately test the hip joint implant products before marketing them to consumers such as Plaintiff, failed to disclose to Plaintiff that such testing had not been

done, and which testing would have disclosed the magnitude of the potential risks associated with the use of the hip joint implant.

160. A final Failure Modes and Effects Analysis (FMEA) table is included in the submission to the FDA as part of the approval process. One of the "potential failure modes" listed was "wear debris generated with mating tapers." The severity is listed as "minor" (not "serious"), and the probability is "low" and not "moderate" or "high."

161. However, the test results of the bench testing show a higher incidence of fretting and chemical accumulation than that predicted by Zimmer.

162. The "level of failure is described Fretting >10% of the contact surface, debris accumulation, discoloration." Separate testing results also observed that fretting debris generated were higher than the "low probability" statement in the FMEA table submitted to the FDA and released to the medical community. That meant that the incidence of fretting and accumulation of debris was more probable than predicted by Zimmer when it submitted this information to the FDA.

163. Zimmer failed to warn of these increased incidents of fretting and corrosion, or that the data demonstrated a greater probability of failure than was initially described to FDA. Zimmer's failure to warn was willful and malicious in that Zimmer's conduct was carried on with a conscious disregard for the safety and the rights of Plaintiff.

164. As a direct and proximate result of being implanted with Zimmer's defective, dangerous, hazardous and unsafe hip implant products, Plaintiff Mary Jo Liesch has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for herself as a result of the injury and damages she has suffered; and Plaintiff Donald W. Liesch has lost the society, comfort and consortium of

his beloved wife. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

165. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM FIVE

NEGLIGENT MISREPRESENTATION

166. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

167. Zimmer falsely represented to Plaintiff, her physicians, and other members of the general public, that Zimmer's hip joint implant products were safe for use in hip replacement surgery; were fit for their intended purposes; that Zimmer's hip joint implant products were not dangerous and did not impose any health risks; did not cause metallosis or the release of metal debris because the femoral ball was metal and the cup was polyethylene; the doctors were not informed of the risk of mixed metals at the junctures which caused trunnionosis; and that Zimmer's hip joint implant products would function without defect. The representation by Zimmer was, in fact, false. The true facts were that Zimmer's hip joint implant products were not safe for use in hip replacement surgery and were, in fact, dangerous to the health and body of Plaintiff and their intended consumers.

168. Defendants, by their Executives, Directors, Staff and/or Research Engineers and/or other employees expressly warranted in its written literature, advertisements and representations of its representatives and agents that:

a. The hip implant was safe, effective, fit and proper for the use for which it was intended and for future use;

b. The hip implant would not fail during normal usage and would perform for its proper use in the future;

c. The hip implant would not develop corrosion, metal figure or stress fractures;

d. The hip implant was properly designed, manufactured and included adequate warnings about the risks involved in their use;

e. The hip implant used adequate materials that were not susceptible to corrosion, metal fatigue, stress fracture and failure;

f. The hip implant minimized stress concentrations on the neck/stem components;

g. Defendants adequately studied and/or tested the hip implant for the possibility of developing corrosion, metal fatigue, stress fracture and/or failure;

h. The hip implant was inspected for signs of corrosion, metal fatigue, stress fracture and/or faulty manufacture prior to the device's sale, distribution or supply;

i. Defendants had proper quality control procedures in place with respect to the hip implant;

j. "Years of extensive engineering design, laboratory testing and clinical consultation have been devoted to optimize the structural integrity [and] wear debris characteristics…of the implants and instruments";

k. "The neck and stem components of the Zimmer M/L Taper with Kinectiv Technology have passed extensive laboratory fatigue testing";

l. "The strength requirements led to the deliberate design of the proximal stem geometry as well as the amount of version provided by the neck components";

m. "The implants for performance fatigue testing were carefully selected via bench testing and exhaustive Finite Element Analysis to ensure that the worst case combinations of components were tested in anteverted, straight and retroverted configurations";

n. Defendants used "long-term clinical retrieval feedback of modular junctions that have been used successfully for many years [and] developed a challenging test to replicate the most aggressive clinical fretting corrosion response";

o. That "Tivanium® Ti-6Al-4V Alloy provides excellent biocompatibility and strength without excessive stiffness."

169. Zimmer made the above-mentioned representations with no reasonable ground for believing them to be true. Zimmer did not have accurate or sufficient information concerning the representations, and Zimmer were aware that without such information, they could not accurately make the representations.

170. To compare the performance of the Zimmer implant used in Plaintiff's original total hip arthroplasty procedure, data from national joint replacement registries can be analyzed. There are at least eleven (11) different national registries that collect information on joint replacement data. National joint replacement registries are databases that compile information on arthroplastic procedures. One of the largest of these registries is the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). As of its last publication (2015), it had collected data from over 988,000 primary and revision procedures between 1999 and 2014. Of these, the registry has recorded 296,550 primary total hip replacement procedures.[AOANJRR 2014 report, pg 68] As of the 2014 annual report, the cumulative failure rates of THA components at 1, 3, 5, 7 years post-implant are 1.6%, 2.8%, 4.0% and 5.2%,

respectively. [AOANJRR 2014 annual report, pg 68] The AOANJRR also identified particular implants that performed less well than the set of implants as a whole.

171. The AOANJRR data indicate that the Zimmer M/L Taper with Kinectiv Technology was first used in Australia in 2008. Through 2014, 2,843 of these devices were implanted. The Zimmer M/L Taper with Kinectiv Technology was specifically identified by AOANJRR as early as the 2013 annual report as having revision rates significantly higher than other total hip arthroplasty prosthetics, with revision rates greater than 2 times that of other conventional hip implants. The most prominent cause of these unusually high revision rates was "metal-related pathology", which was more than 12 times more likely to be the reason for a revision surgery with the M/L Taper Kinectiv compared to other total hip arthroplasty systems.

172. Plaintiff's cause for revision was metal-related pathology. At the time the above-mentioned representations were made, Zimmer concealed from Plaintiff and her surgeon the information that was being generated from the post marketing surveillance of the implantation of the devices during the period from 2007 through 2014.

173. At the time the representations were made by Zimmer, and at the time Plaintiff and her physicians took the actions alleged in this Complaint, Plaintiff and her physicians were ignorant of the falsity of Zimmer's representations.

174. In reliance on Zimmer's representations, Plaintiff and her surgeon were induced to, and did, use Zimmer's hip joint implant in hip replacement surgery. Plaintiff's surgeon relied on the medical conferences and the journal articles to get information about the safety of the devices. However, the journal articles and the medical conferences did not have the information that became available through the Australian registry in 2013.

175. Had Plaintiff known the actual facts, she would not have permitted her surgeon to proceed as usual, using the Zimmer components. And had Plaintiff's surgeon been informed, it is unclear how he would have handled the information. He went blindly into the surgery, relying on the concealed information and the misrepresentations made to the FDA and the public that there was not an increased rate of revisions due to metal pathology.

176. Plaintiff's surgeon, a seasoned physician who was trained to rely and expect information that he believed was accurate and truthful. Zimmer failed to deliver that accurate, truthful and complete information to the medical community, to the journals, to the teaching doctors and ultimately to Plaintiff's surgeon during the period from 2007 through after Plaintiff's total hip arthroplasty.

177. The reliance of Plaintiff and her physicians on Zimmer's representations was justified because the representations were made by individuals and entities that appeared to be in a position to know the true facts and to be the experts.

178. Plaintiff's reliance on Zimmer's representations was justified because Zimmer were in a special or fiduciary relationship directly and through her health care providers with Plaintiff, and Plaintiff reasonably relied upon Zimmer's representations concerning the product, having no independent expertise of her own to evaluate the product or the representations to be anything other than what Zimmer stated.

179. As a proximate result of Zimmer's false representations and concealment, Plaintiff was caused to sustain the injuries and damages described in this Complaint.

180. As a direct and proximate result of Zimmer's conduct, Plaintiff Mary Jo Liesch has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for herself as a result of the

injury and damages she has suffered; and Plaintiff Donald W. Liesch has lost the society, comfort and consortium of his beloved wife. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

181. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM SIX

FRAUDULENT MISREPRESENTATION AND CONCEALMENT

182. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

183. Throughout the relevant time period, Defendants knew that the Zimmer hip joint implant products were defective and unreasonably unsafe for its intended purpose because it was associated with metallosis, trunnionosis, high cobalt and/or chromium levels, corrosion, pseudotumors, adverse tissue reaction and/or necrotic tissue, need for revision and/or explanation, and other adverse medical conditions as described herein.

184. Defendants were under a duty to Plaintiff and Plaintiff's physicians to disclose and warn of the defective nature of the Zimmer hip joint implant products because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the Zimmer hip joint implant products;

b. Defendants knowingly made false claims about the safety and quality of the Zimmer hip joint implant products in the documents Defendants provided to the FDA, physicians, and the general public;

c. Defendants fraudulently and affirmatively concealed the defective nature of the Zimmer hip joint implant products from Plaintiff and Plaintiff's physicians;

d. In 2006, Defendants failed to disclose the accurate information to the FDA. Zimmer downplayed the accurate results of the bench testing that demonstrated more than 10% increased incidents of fretting and corrosion in the FMEA report;

e. In 2008 through 2014, Zimmer failed to disclose the adverse post marketing events that were occurring in Australia, where these devices performed comparatively more poorly than the comparator devices and where there was an increased incidence of metal pathology—exactly the problem that resulted from corrosion and fretting.

185. The facts concealed or not disclosed by Defendants to Plaintiff and Plaintiff's surgeon were material facts that a reasonable person would have considered to be important in deciding whether or not to undergo a procedure or surgery using the Zimmer hip joint implant products.

186. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's surgeon from acquiring material information regarding the lack of safety and effectiveness of the Zimmer hip joint implant products, and are subject to the same liability to Plaintiffs for Plaintiffs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Zimmer hip joint implant products' lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from discovering the truth.

187. As a direct and proximate result of Zimmer's conduct, Plaintiff Mary Jo Liesch has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for herself as a result of the injury and damages she has suffered; and Plaintiff Donald W. Liesch has lost the society,

comfort and consortium of his beloved wife. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

188. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM SEVEN

NEGLIGENCE *PER SE*

189. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

190. Zimmer has an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, and warning of risks and dangers of the Products.

191. Zimmer's acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se*.

192. Zimmer failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, *inter alia*, failing to report each adverse event experience concerning the Products that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by Defendants, failing to promptly investigate all adverse event experiences concerning the Products that are the subject of these postmarketing 15-day Alert reports, failing to submit follow up reports within 15 calendar days of receipt of new information or as requested by the FDA, and, if additional information is not obtainable, failing to maintain records of the unsuccessful

steps taken to seek additional information. Defendants' failure to meet these requirements is evidence of defendants' negligence and constitutes negligence *per se*.

193. Consistent with 21 C.F.R. § 314.70(c) (known as the "changes being effected" regulations), Defendants had and continue to have a duty to initiate a change to the olmesartan products' labels to reflect the true levels of risk, including the risk of developing Plaintiff's injuries complained of herein. To this day, Defendants have not adequately satisfied their duty to update the Products' prescribing information to reflect their knowledge as to the true risks of developing the injuries complained of herein. Defendants' failure to meet these regulatory requirements is evidence of Defendants' negligence and constitutes negligence *per se*.

194. Plaintiff, as a purchaser, of the Products, is within the class of persons the statutes and regulations (described above) are designed to protect and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

195. As a direct and proximate result of Zimmer's acts and omissions, Plaintiff Mary Jo Liesch has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for herself as a result of the injury and damages she has suffered; and Plaintiff Donald W. Liesch has lost the society, comfort and consortium of his beloved wife. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

196. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM EIGHT

PUNITIVE DAMAGES

197. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

198. At all times herein referenced, officers, directors, and managing agents of Zimmer knew, and were aware, and concealed, hid, and/or otherwise downplayed the true risks of Zimmer hip joint implant products.

199. At all times herein referenced, officers, directors, and managing agents of Zimmer knew, and were aware, that the Zimmer hip joint implant products was associated with metallosis, trunnionosis, high cobalt and/or chromium levels, corrosion, pseudotumors, adverse tissue reaction and/or necrotic tissue, need for revision and/or explanation, and other adverse medical conditions as described herein

200. Zimmer designed, engineered, developed, manufactured, fabricated, assembled, equipped, tested or failed to test, inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied, distributed, wholesaled, and sold the Zimmer hip joint implant products, products which Defendants knew to be dangerous and unsafe for the purpose for which it was intended to be used.

201. At all times herein mentioned, prior to and at the time that Defendants designed, engineered, developed, manufactured, fabricated, assembled, tested or failed to test, promoted, marketed, supplied, distributed, and/or sold the Zimmer hip joint implant products to Plaintiff and Plaintiff's physicians, and prior to the time that the product was used, Zimmer knew, or should have known, that the Zimmer hip joint implant products were defectively designed and manufactured, that it had extremely dangerous properties and defects, and that it had defects which would cause serious injuries and damage to users of said product, thereby threatening the

life and health of the users. Further, at all times, all Defendants knew that the Zimmer hip joint implant products had caused serious injuries and damage to other members of the public.

202. At all times herein mentioned, Zimmer, despite actual knowledge described herein, intentionally suppressed the complaints and adverse events, actively concealed and downplayed the risks associated with the Zimmer hip joint implant products, actively promoted the Zimmer hip joint implant products, failed to warn Plaintiffs and the medical community of the true risks associated with the Zimmer hip joint implant products, saturated the scientific and medical literature with biased, industry-funded studies to conceal the true risks of the Zimmer hip joint implant products, and otherwise failed to warn Plaintiffs, the medical community, of the true risks of the Zimmer hip joint implant products.

203. At all times herein mentioned, Zimmer had actual knowledge of the facts hereinabove alleged demonstrating that serious injuries occur to patients in whom the Zimmer hip joint implant products were implanted. Nevertheless, Zimmer deliberately suppressed, concealed, downplayed, and/or otherwise hid any information demonstrating the true risks associated with the Zimmer hip joint implant products from Plaintiffs, the medical community, and/or the general public Zimmer continued, and continues, to actively promote the Zimmer hip joint implant products to orthopedic surgeons in an effort to maintain and increase the Zimmer hip joint implant products enormous profitability.

204. As a legal and proximate result of Zimmer's misconduct, callous, disregard, and omissions as alleged, Plaintiffs sustained the injuries, damages and losses described.

205. Zimmer's conduct and omissions in allowing such an extremely dangerous product to be used by members of the general public, including Plaintiffs, constitutes fraud,

malice and oppression toward Plaintiffs and others, and demonstrates a callous and intentional disregard of the rights of Plaintiffs and others.

206. Plaintiffs are therefore entitled to exemplary or punitive damages, which would serve to punish Zimmer and to deter wrongful conduct in the future.

CLAIM NINE

LOSS OF CONSORTIUM

207. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

208. Mary Jo Liesch was and still is the lawful wife of Plaintiff Donald W. Liesch.

209. As a result of Zimmer's actions, Plaintiff Donald W. Liesch has been deprived of the consortium of his wife, including, but not limited to, her services, love, companionship, affection, society, loss of physical relations and solace.

210. The damages sustained by Plaintiff Donald W. Liesch are a direct and consequential result of the action or inaction of negligence and palpable negligence of Zimmer.

211. As a result of Zimmer's negligent and outrageous conduct, by its agents, servants and/or employees, described herein, Zimmer acted with gross reckless disregard for the probability of causing Plaintiff Donald W. Liesch, to suffer severe emotional distress and loss of the consortium of his wife.

212. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants, and each of them, in an amount which exceeds the jurisdictional limits of all lower courts, together with interests, costs, and disbursements of this action, including damages including, but not limited to:

a. Compensatory damages in excess of the jurisdictional amount of this Court, in an amount to be proven at trial;

b. Exemplary damages to be proven at trial;

c. Incidental, hospital, and medical expenses according to proof;

d. Punitive damages for the wanton, willful, fraudulent, reckless acts of Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and to deter future similar conduct;

e. Loss of consortium damages on behalf of Plaintiff's spouse;

f. For reasonable attorneys' fees and costs;

g. For pre-judgment interest; and

h. For such further and other relief the Court deems just, equitable, and proper.

Dated: July 26, 2017

Respectfully submitted,

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JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: July 26, 2017

Respectfully submitted,

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